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10/623,458	07/17/2003	Baback Gharizadeh		3111

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/623,458

Applicant(s)

GHARIZADEH, BABACK

Examiner

Christopher M. Babic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/13/06
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1-12 are pending. The following Office Action is in response to Applicant's response dated September 1, 2006.

### ***Sequence Rules Compliance***

In view of Applicant's amendment to the specification, the instant application now complies with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures set forth in 37 C.F.R. §§ 1.821-1.825

### ***Claim Objections***

The objections of claims 4-12 have been withdrawn in view of Applicant's amendments. Thus, claims 4-12 will be further treated on the merits.

### ***Claim Rejections - 35 USC § 112 - 2nd Paragraph***

The previous rejections of claims 1-3 have been withdrawn in view of Applicant's amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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The following new ground(s) of rejection is made in view of Applicant's amendments.

**Claims 5-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

(a) Claims 5-12 are indefinite because it is unclear, when the method is required to contain multiple types or species, as in claim 5, whether the species region of interest for example is required to have different nucleotide patterns. Step (a) requires each "type" region of interest for example to have different nucleotide patterns, however, makes no reference as to whether each "species" region of interest for example.

(b) Claim 9 recites the limitation "the general or consensus primer" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 is further indefinite because the metes and bounds of the phrase, "the sequence distance from the 3'-end" is unclear. The phrase does not recite a finite distance.

Claim 9 is further indefinite because it is unclear whether limitations following the phrase, "could be" are required by the method. Furthermore, it is noted that additional method steps must be recited in an active manner.

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(c) Claims 10-12 introduce limitations that are narrative in form and replete with indefinite and functional or operational language. Additional method steps must be recited in an active manner.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following new ground(s) of rejection is made in view of Applicant's amendments.

**Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rady et al. ("Type-specific primer-mediated direct sequencing of consensus primer-generated PCR amplicons of human papillomaviruses: a new approach for the simultaneous detection of multiple viral type infections. J Virol Methods. 1995 Jun;53(2-3):245-54").**

With regard to claim 1, Rady et al. teach a method (page 246-249, materials and methods; figure 1, for example) comprising the steps of: (a) providing a sample

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containing nucleic acid molecules (page 246, materials and methods, paragraph 1; figure 1, for example); (b) providing a mixed pool of at least two sequencing oligonucleotide primers (page 246, 247, materials and methods; figure 1, for example), whereby each primer is designed for being specific for one type or species or group or target chosen from the known set of types or target of the nucleic acid sample, thereby allowing a primer, which is specific for a type, species, group or target that is present in the sample, to hybridize in or close to the target or variable region (figure 1; table 1, for example); (c) mixing the sample and mixed pool of specific primers under conditions allowing a primer or primers to hybridize if a target type or types are present in the sample (page 246, 247, materials and methods; figure 1, for example); (d) determining the type, species or target region to which the primer or primers have hybridized by extending the hybridized primer or primers in a DNA sequencing reaction (pages 248, 249; figures 2, 3, for example).

With regard to claim 2, Rady discloses nucleic acid sequencing methods (pages 248, 249; figures 2, 3, for example).

With regard to claim 3, Rady discloses the human papillomavirus (HPV) (page 246, 247, materials and methods; figure 1, for example).

With regard to claim 4, it is noted that the instant claim requires only the providing of a nucleic acid sample. However, the nucleic acid sample taught by Rady necessarily contains two target DNAs as well as multiple types of HPV (pg. 250, 1st para., for example).

With regard to claim 5, Rady discloses a nucleic acid sample containing multiple types of HPV (pg. 250, 1st para., for example).

With regard to claim 6, Rady discloses at least one primer specific for a type of HPV (pages 248, 249; figures 2, 3, for example).

With regard to claim 7, Rady discloses HPV (page 246, 247, materials and methods; figure 1, for example).

With regard to claim 8, Rady discloses HPV-16 (pg. 250, 1st para., for example).

With regard to claims 9-12, due to the indefiniteness of each claim (see above 112, 2nd section), the scope is unclear. The teachings of Rady appear to anticipate the intended limitations of the instant claims. Rady teaches the amplification of a conserved region within multiple different HPV types and subsequent sequencing with sequence specific primers (page 246-249, materials and methods; figure 1, for example).

### ***Response to Arguments - Claim Rejections - 35 USC § 102***

Applicant's arguments with respect to the previously applied references have been fully considered but they are not persuasive.

#### **Rejection of claim(s) 1-3 over Rady**

Applicant argues that since Rady neither teaches nor suggests employing a mixed pool of oligonucleotide primers for genotyping, typing, identification, detection and sequencing nucleic acid molecules from a range of different types of samples, Rady does not anticipate claims 1-3 of the present invention. Applicant further asserts that in

fact teaches Rady teaches away from the invention, because Rady teaches multiple sequencing reactions using single type-specific HPV primers, while the present invention employs a single sequencing reaction using a plurality of type-, species-, group-, and/or target-specific primers for examining a single sample of nucleic acid molecules. These arguments are not persuasive because the claimed invention does not require providing two *distinct* or *different* sequencing primers in a single sequencing reaction. Applicant is correct in asserting that Rady teaches the identification of a single species of HPV infection within a mixed sample of infection by employing a single type-specific primer, however, neither step (b) of claim 1, nor any other dependent limitation in any subsequent claim actually requires the "at least two sequencing primers" to be structurally different from each other. Thus, the teachings of Rady encompass the claimed invention because the sequencing reactions necessarily contain at least two sequencing primers, where each primer is designed to be specific for one type or species or group or target, as required by the claimed invention.

With specific regard to the term, "mixed pool," absent any formal or express definition within the specification, the term is given its broadest reasonable interpretation. During examination, limitations appearing in the specification but not recited in the claim should not be read into the claim (see MPEP 2106). It is submitted that a "mixed pool" of at least two sequencing primers is encompassed by the teachings of Rady, who disclose a sequencing reaction with multiple primers of identical structure.

Thus, the rejections are maintained.



**Conclusion**

**Claims 1-12 are rejected.**

**No claims are allowed.**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Makridakis et al. ("Multiplex automated primer extension analysis: simultaneous genotyping of several polymorphisms" *Biotechniques*. 2001 Dec;31(6):1374-80.

Makridakis teaches multiplex primer extension analysis comprising multiplexing four primers, each corresponding to 4 positions (fig. 1, for example).

Ye et al. ("Fluorescent microsphere-based readout technology for multiplexed human single nucleotide polymorphism analysis and bacterial identification" *Hum Mutat*. 2001 Apr;17(4):305-16. Ye teaches a microsphere-based single base extension reactions for multiplex genotyping analysis (fig. 1, for example).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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 11/29/06

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11/30/06